## SECTION SEVEN

## SUMMARY

As referenced in the clinical studies and documentation provided in Section Six, creatine from creatine ethyl ester HCl, is a well characterized dietary ingredient that has been available in the marketplace and successfully used for muscular health for a significant amount of time. The ethanol component of the source ingredient creatine ethyl ester HCl is also well characterized, and its safety for food use has long been established and recognized by FDA.

The level of use for creatine from creatine ethyl ester HCl for adults only will be at a level of 500 mg to 3 grams per day. Based on the fact that creatine from creatine ethyl ester HCl is more available to the body, its level of use will be well below the typical marketplace use of creatine monohydrate.

The ChemPharma Int'l. study that was coordinated with FDA clearly establishes that after oral administration of creatine from creatine ethyl ester HCl dissociates to creatine and ethanol (Attachment 24). The second ChemPharma Intl. study shows conclusively that the bioavailable dietary ingredient created in the body when administered in the form of creatine ethyl ester is creatine rather than the intact (associated) ethyl ester (Attachment 25). Based on the long history of use and safety studies identified in Section Six, the distributor of creatine from creatine ethyl ester HCl considers their documentation sufficient to provide a reasonable basis for creatine being considered safe for use.